



INTERNATIONAL
HELLENIC
UNIVERSITY

Patent Law and the Pharmaceutical Industry

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A thesis submitted for the degree of

Master of Arts (MA) in Art, Law and Economy

January 2017

Thessaloniki – Greece

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Abstract

This dissertation was written as part of the MA in Art, Law and Economy at the International Hellenic University.

In this dissertation, there will be an analysis of pharmaceutical patents and some issues that are created due to their existence. In the first chapter, there will be an analysis of what is medicine, which are its types and especially an analysis of generics, since they play a major role in the pharmaceutical industry.

In the second chapter, there will be an analysis of the types of pharmaceutical patents and the special certificate for pharmaceuticals, the supplementary protection certificate. Moreover, the economical and technological use of pharmaceutical patents will also be discussed. The interaction of archetypes and generics in the pharmaceutical industry affects this industry through aspects such as competition, parallel import, licenses and access to medicines, issues that will be discussed in the third and fourth chapter. Some case study will be provided concerning not only these issues, but also other great issues, such as the AstraZeneca case, that have affected the pharmaceutical industry. Finally, some conclusions that were made after this research will be provided in the last chapter.

Keywords: competition, generics, medicines, patent, pharmaceutical.

Eleni Beka

22 January 2017

Preface

Hereby is my dissertation “Patent law and the Pharmaceutical Industry”. It has been written to fulfill the graduation requirements of the M.A. in Art, Law and Economy at the International Hellenic University (I.H.U.). I was engaged in researching and writing this dissertation from September 2016 to January 2017.

The research on this dissertation was undertaken after the title was accepted by the University. The research was difficult, but extensive investigation and my personal strong will and hardworking temper allowed me to form the final text.

I would like to thank my supervisor for his guidance and support during this process. I would also like to thank all the University’s faculty for their help and support. Especially, I would like to thank Prof. Kaissis Athanassios, who was my professor during my undergraduate program and my mentor during my postgraduate program, for his academic example and his constant source of inspiration and Prof. Komnios Komninos for his devotion towards students and their academic achievements.

This dissertation could not be completed without the unconditional support of my parents, Bekas Michail and Koliou Sophia, and my sister, and future colleague lawyer, Beka Elisavet. Their efforts and care will be motivating me to conquer all my goals.

I hope you have a pleasant reading.

Beka M. Eleni

Thessaloniki, January 22, 2017.

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Introduction

Intellectual Property Law is the area of law that concerns legal rights that associate with creative effort or commercial reputation.¹ There are many reasons behind the existence of Intellectual Property. Some of them are the encouragement of innovation, cultural development and the development of global commercial transactions and marketing.²

Patent Law is one kind of Intellectual Property Rights and it concerns new, industrially applicable inventions.³ It can be defined as the grant by a state of exclusive rights for a limited time as “reward” for the new and useful invention.⁴ A pharmaceutical patent is granted for an initial discovery.⁵ It gives the pharmaceutical company a monopoly to work, promote and sell the medicine by excluding all the others from it. This monopoly is not an absolute one, since there are some checks and balances. Patents are the most effective choice to protect an invention and its investment.⁶

Patents exist only as provided in the national law of every state, and can be enforced only to the extent that application has been made and a patent granted covering the territory of an individual state.⁷ Thus, they are concerned to generally be limited to the territory of the state that has granted it. Since someone wishes to expand the right to

¹ (Bainbridge, 2007), p. 3.

² (Μαρίνος, 2013), p. 1.

³ (Bainbridge, 2007), p.343.

⁴ (Grubb, 1999), p. 3.

⁵ (Priddis and Constantine, 2011), p. 256.

⁶ (Bainbridge, 2007), p. 343-344.

⁷ (Lehamn, 2003), p.2.

more states, then a separate license must be granted in all of them.⁸ Currently, inventions can be protected in European Union either by national patents, granted by the competent national Intellectual Property authorities in E.U. countries or by European patents granted centrally by the European Patent Office (EPO).⁹ It came into effect in 1977 and applicants could then file a single patent application with the EPO that, if granted, was applicable in all the member – States that the claimant chose.¹⁰ Inventors can also file a claim to the World Intellectual Property Organization (WIPO) in order to request the grant of national patents in any country that is a member in the Patent Cooperation Treaty (PCT). This method is quicker and can provide multiple patents granted in different countries with only one application.¹¹ After the expiry of the patent, the invention falls into the public domain, where everyone can use it.

Pharmaceutical patents play a crucial role for the existence and the development of pharmaceutical industry. In this dissertation, the reasons that pharmaceutical patents are so important will be analyzed, by examining the hidden roles that they have and how they interact with competition, the market and healthcare at the same time. The discussion about patent law and pharmaceutical industry is immense.

First of all, medicines will be defined in order to understand, why pharmaceutical industry is complicated and how one type of medicines, the generics, influences the balance of it. The clash between prototypes and generics need some analysis to understand deeper the problems that occur in the pharmaceutical industry. Moreover, since pharmaceutical patents are more complicated than the other patents, it is vital to define the different types of pharmaceutical patents, which are the main tools used by pharmaceutical companies to protect their innovative inventions. In pharmaceuticals, there is also a different type of intellectual property right that enhances this protec-

⁸ (Grubb, 1999), p. 3.

⁹ (European Commission, 2017).

¹⁰ (Λεφάκης, 2004), p. 121.

¹¹ (WIPO, 2015).

tion, the SPC. Of course, it is important to explain why pharmaceutical patents have both an economical and technological use.

The commercial exploitation of pharmaceutical patents is a huge issue that needs a lot of analysis. Pharmaceutical market works differently compared to other markets, since demand and offer are affected by different and more complicated factors. Competition law in the E.U. interacts with pharmaceutical patents, since their existence seems to promote fair competition and innovation. However, wherever balance is offended, problems rise and strike competitions well-being. Access to medicines seems to be the main problem of both developed and developing countries, since the absolute protection of medicines creates also problems to pharmaceuticals' accessibility. These issues will be examined in this dissertation to understand better and deeper pharmaceutical patents and how they interact with pharmaceutical industry.

WHAT IS A MEDICINE?

Since pharmaceutical patents are to be analyzed, it is essential to first give a definition concerning “medicines”. *Medicine* is a product that has special physical capacity and consists various ingredients in specific quantities that follow a specific procedure. A medicine is considered to become a pharmaceutical product from the moment it is produced in a massive quantity.¹² When a medicine is first developed by a pharmaceutical company, it is sold under this company’s brand name and it is protected by patent law¹³, provided a request for it was filed and granted by the procedure mentioned above. According to the Cambridge Dictionary, “*medicine is a substance that cures an illness or an injury*”.¹⁴

TYPES OF MEDICINES

Generally, *four types of medicines* can be found in the pharmaceutical industry:

- i. *Ethical medicines* (which can be prescribed by a medical practitioner),
- ii. *Over – The – Counter (O.T.C.) medicines* (which are not prescribed by a medical practitioner),
- iii. *Generic medicines* (analyzed below),
- iv. *Biotech medicines*.¹⁵

¹² (Καφετζής, 2013), p. 16.

¹³ (Mandal, 2014).

¹⁴ (Cambridge Dictionary, n.d.).

¹⁵ (Φαρμάκης, 2012), p. 14.

After the implementation of paragraph 6 of the *Doha Declaration on the TRIPs Agreement and public health in 2003*, a new definition concerning medicines started to exist. According to it, *“pharmaceutical product”* means *“any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.”*¹⁶

As far as the E.U. is concerned, the *Directive 2001/83/EC* provides rules relating to medical products for human use. Article 1 (1) refers to *“proprietary medical product”* as *“any ready – prepared medical product placed on the market under a special name in a special pack”*. Article 1 (2) provides a definition for *“medical product”*. According to this definition, medical product is *“any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.”*¹⁷ There are also more definitions concerning the different kind of medicines that exist, such as immunological medicinal product, homeopathic medicinal product, radionuclide precursor, etc. It can easily be concluded that the differences that exist between the different kind of medicines is the reason behind the heterogeneous prices of medicines.¹⁸ The medical products that are protected by patent law are known as *“original”* or *“organic”* or *“innovator”* medical products.¹⁹

¹⁶ (World Trade Organization, 2003).

¹⁷ (Official Journal of the European Union, 2001).

¹⁸ (Καφετζής, 2013), p. 18.

¹⁹ (Viorel, 2015), p. 10.

GENERIC MEDICINES

Another category of medicines, which is also well – known, is this of “*generic medicines*” or “*generics*”. A generic medicine is identical or bioequivalent to a brand name one in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generics are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.²⁰ Generic medicines are legal copies of the “archetype” medicines (the “prototypes” or “innovator” medicines or “originals”).²¹

WHY DO THEY EXIST?

One of the reasons behind their existence is of course *an economic one*. Prototypes are really expensive and can bring a lot of profit to pharmaceutical companies that own them. It is logical that other pharmaceutical companies want a piece of profit made from a medicine in the pharmaceutical market. No matter how protected medicines may seem to be, patent is not powerful enough to protect an archetype medicine after its expiration. Of course there are also other reasons behind generics’ existence.

Pharmaceutical patents have *two special characteristics*. They expire after an amount of time (limited life duration of approximately 20 years in E.U.) and they exist only in the country where they were granted. Thus, generic drugs can be produced and sold freely in the market whether the license of the archetype medicine has expired or whether a license was not granted in this specific country’s territory.

To sum up, generics can be produced when one or more of the following facts exist:

- i. The pharmaceutical patent that protects the prototype has expired.

²⁰ (U.S. Department of Health and Human Services, 2015).

²¹ (Καφετζής, 2013), pp. 30-31.

- ii. The pharmaceutical company that produces a generic proves that there is no infringement as regards the generic and the prototype's patent or that the pharmaceutical patent is null and void.
- iii. The archetype medicine was never protected by a patent.
- iv. The archetype medicine is not protected by patent law in the country where the generic is produced.²²

As it can be concluded, generic medicines' existence is the result of pharmaceutical patents' existence. In my opinion, there is an obvious interaction between pharmaceutical patents and generics. The end of a patent is to be considered the beginning of a generic. If patents did not exist, generics would not exist either. If there was no protection, chaos would exist and there would be no distinction between an archetype medicine and a generic one. Patent law provides the balance needed in order to enhance a healthy pharmaceutical industry that constitutes a strong market not only nationally but also internationally.

TYPES OF GENERICS

It is normal that not all the generic medicines circulated in the pharmaceutical market are the same. There are different types of them:

- i. The *"unbranded"* or *"commodity"* generics. This kind of generics is circulated in the pharmaceutical market with the International Non – proprietary Name (INN) of its active chemical substance and is defined by the World Health Organization (WHO).²³
- ii. The *"brand"* generics. These generics are circulated in the pharmaceutical market with their new reserved brand name or trademark, since they are final products. Brand generics have both chemical substance and capacity similar to the prototype.

²² (Καφετζής, 2013), pp. 30-31.

²³ (Καφετζής, 2013), p. 31.

- iii. The “*copy products*”. The copy products have a main difference compared to other generics. They tend to copy a prototype medicine for which a pharmaceutical patent exists and is active.²⁴ This act is considered to be an infringement and there are provisions that prohibit it in the states’ legislation.

THE “CLASH” BETWEEN GENERICS AND PROTOTYPES

According to a research group in Boston U.S., there is no difference between generics and prototypes and that can affect in a positive way the life of millions of people all over the world. During the economic crisis, especially in countries such as Greece, the existence of cheaper medicines that have the same effects as the prototypes is more than vital for a patient. It is logical that generics cannot supplant the archetype medicines 100 per cent. Of course the important thing is that the patient’s health can be secured with the consume of “cheaper” medicines.²⁵ Generics are subject to the same rules concerning the manufacture and pharmacovigilance and have the same quality, efficiency and safety characteristics as the prototype medicines.²⁶

Generic medicines seem to be really famous in the pharmaceutical market, since their cost is lower. As it is stated by the Medicines for Europe (former European Generic Medicines Association EGA), “*more than 56% of prescriptions of dispensed medicines in Europe are generic yet they account for just 22% of the total expenditure on medicines. Without competition from generic medicine manufacturers, this level of access would cost Europe an additional €100 billion every year.*”²⁷ Nowadays, almost 12 pharmaceutical companies that produce prototypes also operate subsidiary companies that specialize in the production of generis (Figure 1: Subsidiary and prototype companies).

²⁴ (Καφετζής, 2013), p. 32.

²⁵ (Φαρμάκης, 2012), p. 53.

²⁶ (Viorel, 2015), p. 11.

²⁷ (Medicines for Europe, n.d.).

SUBSIDIARY COMPANY	PROTOTYPE COMPANY
Apothecon	Bristol – Myers Squibb
Arcola Laboratories	Aventis (Rhone Poulenc Rorer)
Blue Ridge Laboratories	Aventis (Hoechst Marion Roussel)
Copley Pharmaceutical	Aventis (Hoechst Marion Roussel)
Dista Products	Eli Lilly
Elkins – Sinn	Wyeth (American Home Products)
ESI – Lederle	Wyeth (American Home Products)
Geneva Pharmaceuticals	Novartis
Greenstone	Pfizer (Pharmacia & Upjohn)
IPR Pharmaceuticals	Astra Zeneca
Kanetta Pharmacal	Sanofi Winthrop
Lederle Laboratories	Lederle Standard Products
Penn Labs	Glaxo Smithkline
Schein Laboratories	Bayer

Figure 1: Subsidiary and prototype companies

Source: (Γκόλνα, Κοντιάδης and Σουλιώτης 2005), p. 51.

It is only logical that there would be a clash between prototypes and generics. First of all, neither science nor legislation has defined whether clinical trials for generics are allowed to begin before the exhaustion of a pharmaceutical patent.²⁸ Whether such a fact is permitted a generic will be able to be circulated in the pharmaceutical market from the exact moment the archetype's patent has expired. The WHO has not yet defined the issue. As a result, the U.S. and Canada use the "*Bolar*" provision, which allows all the pharmaceutical companies that manufacture generics to perform clinical trials, produce and store their generics before the exhaustion of pharmaceutical patents. However, such a provision does not exist in the E.U..²⁹ It is only normal that there are disputes between these countries.

²⁸ (Γκόλνα, Κοντιάδης and Σουλιώτης 2005), p. 52.

²⁹ (Γκόλνα, Κοντιάδης and Σουλιώτης 2005), p. 52.

On the one hand, the European Union (EU) is treating generics in a positive manner.³⁰ The reason behind this positive attitude is that generics will decrease the cost of health and social insurances given by the governments of the member – States.³¹ According to *Medicines for Europe*, generics are the heart of public health delivery. The *5 pillars of generics* are that *first*, generics are for patients and can create a better-value healthcare. *Second*, generics stand for quality, since in order to be released to the market they have to be approved and tested really strictly, according to E.U. and national regulations and legislation. *Third*, generic medicines create greater economic value in the supply of medicines, since fair and healthy competition in the pharmaceutical market is promoted, in the support of healthcare investments' sustainability and in the promotion of a positive macroeconomic impact as regards the pharmaceutical industry. *Fourth*, generics enhance sustainability as far as safe and effective treatments for European patients are concerned. *Fifth*, the generic medicines industry is devoted to partnership with the healthcare industry and the legislation, so that access to medicines is ensured for every patient.³²

On the other hand, this can harm the profit made by the pharmaceutical company that produces and sells the archetype medicine. This profit made is used by pharmaceutical companies for the enhance of research to create more medicines and improve the ones that already exist. Is it safe to decrease their profit in such an amount that further research would then be impossible? A prototype drug is the result of years of studies, research and money spent by scientists and pharmaceutical companies. However, there are incidents where a pharmaceutical company tries to secure profit by misusing pharmaceutical patents.

In my opinion, the promotion of generics is vital for the limitation of monopoly. Of course, pharmaceutical companies that create new archetype medicines should be

³⁰ (Καφετζής, 2013), pp. 32-33.

³¹ (Καραγιάννης, 2013), p. 1.

³² (Medicines for Europe, n.d.).

protected both economically and technologically. That is why pharmaceutical patents exist. Inside a market, the stronger part cannot be equipped with all the means that protect itself against the weaker one. It is fair enough that balance is provided, so that both parties have equal protection and opportunities for profit. Since pharmaceutical companies that can create new innovative medicines can protect their creations through patents, the less strong ones in the market share should be able to create and circulate their generics in it after the expiration of the patent. If balance is kept, then there will be no harm for the profit of prototypes, but also there will be no harm for the generics pharmaceutical companies. Both these kinds of companies should exist for a healthy and fair pharmaceutical market to exist and flourish. The WHO has stated that *“Competition is the most powerful mean of politics used to decrease the price of medicines that their patents have expired...”*³³

³³ (Καφετζής, 2013) pp. 122-123.

PATENTS AND PHARMACEUTICAL INDUSTRY

The American virologist Jonas Edward Salk had to work really hard for almost seven years in order to discover the vaccine that can cure poliomyelitis. After World War II (W.W.II), polio was number one threat for mankind, since in 1952, in the U.S., 58,000 people were infected. The virus killed 3,145 people and 21,269 were disabled. The discovery of this vaccine in 1955 was a huge relief for mankind, since millions of people were saved from certain death or paralysis. Until now, children from all over the world are getting this specific vaccine to prevent an infection. It can be presumed that this could make a profit of billions of dollars, whether someone had protected it via patent law. However, when Jonas Edward Salk was asked who owns the new vaccine for polio, he answered, *“...I would rather say the world. There is no patent. Can anyone patent the sun?”*³⁴

DIFFERENT TYPES OF PHARMACEUTICAL PATENTS

Pharmaceutical patents are more complicated than the other ones. That is logical, in my opinion, considered that medicines are not simple chemical products, but, on the contrary, they involve more than one substances and procedures used to manufacture them. In the pharmaceutical industry, more than one types of patents exist (Figure 2: Example of European Patent Certificate). The basic categories of pharmaceutical patents are:

³⁴ (Μανδραβέλης, 2015).

i. The “*composition patent*” (*product patent*). This patent is the strongest one and protects the actual active chemical substance in a medicine. Once a medicine is protected by a composition patent, no other pharmaceutical company is able to produce, sell or import that chemical substance. If that happens, it is clearly and infringement of the patent right.³⁵

ii. The “*use patent*”. This patent covers the use of a medicine to cure a disease. It concerns the new medical use of an unprotected or an already protected medicine.³⁶ This kind of right can be protected in some countries, such as the U.S. and Germany, but unfortunately, the U.K. and other countries do not recognize it yet.³⁷

iii. The “*formulation – composition patent*”. This patent concerns the pharmaceutical dosage form on a medicine.³⁸

iv. The “*process patent*”. This patent protects the chemical or any other process that is used to manufacture the medicine, while the chemical product itself is not protected by patent law. Since it is usually very difficult to prove whether a

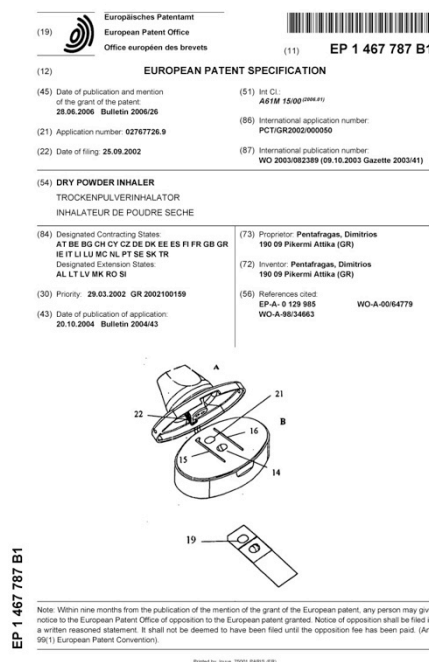


Figure 2: Example of European Patent Certificate

Source: Elpen Pharmaceutical (2016), <http://www.elpen.gr>.

³⁵ (MPA, n.d.).

³⁶ (Γκόλνα, Κοντιάδης and Σουλιώτης, 2005), p. 47.

³⁷ (MPA, n.d.).

³⁸ (Γκόλνα, Κοντιάδης and Σουλιώτης, 2005), p. 47.

pharmaceutical company has been using a patent protected process, many countries have legislation that provides a reversed burden of proof. Thus, the company accused of being infringing a patent is the one responsible to prove that such an infringement does not actually exist.³⁹

- v. The “*evergreening patent*”. This kind of patent is granted to improved or modified medicines that have been already protected.⁴⁰ There are arguments against the existence of such patents, since the pharmaceutical companies try to gain more time of protection by producing small and of minimum importance changes to their medicines. A well-known example of this kind of dispute is the *Novartis v. Union of India and Others case*, which was finally resolved in 2013 by the Supreme Court of India.⁴¹ According to the judgment, the Court has decided that the anti- cancer Novartis’s medicine “*Glivec*” is not protected by patent law, according to India’s national law, since it is not a new medicine, but a new form of the old one,⁴² even though the same medicine has succeeded its protection as a patent in several countries, such as the U.S., Russia and China. It is my opinion, that evergreening patent is an important form of pharmaceutical patent that should not be taken lighthearted. Regulations and legislation should prevent the misuse of this patent. The abolition of this patent is not the solution. Only if countries create legislation that can be fair, will balance be preserved.

PHARMACEUTICAL SUPPLEMENTARY PROTECTION CERTIFICATE

As it has been already mentioned, the creation of a medicine is not simple enough and demands a great amount of money and constant research for many years. Pharmaceu-

³⁹ (MPA, n.d.).

⁴⁰ (Καφετζής, 2013), p. 56.

⁴¹ (Adams and Adams, 2013).

⁴² (Young, 2013).

tical companies tend to file a claim for a pharmaceutical patent before the release of the medicine in the market to gain the appropriate protection. In E.U., a pharmaceutical patent's life expectancy is 20 years.⁴³ That means that if a pharmaceutical company is granted with a patent before the circulation of the medicine, then the time limitation of 20 years will end earlier, since the medicine would not be released in the market for the total of years.⁴⁴ It is normal that this fact cause unrest to the pharmaceutical companies and their investors.

To find a fair solution to this problem, the U.S. and Japan created new provisions that provided with an extension of the time limitation of the pharmaceutical patent. After the first step that was made by these countries, the E.U. was pressed to bring in life similar measures. Although the European Patent Convention (EPC) provided a fixed 20-year patent, the E.U. decided to create a new form of intellectual property right, the *Supplementary Protection Certificate (SPC)*. In 1992, the EU Council created Regulation 1768/92 that provided SPC for the pharmaceutical patents based on national or European patents. The SPC has an effect after the expiry of a pharmaceutical patent. Its duration is equal to the time spent between the filing for a patent and the first grant of authorization of the market of the European Economic Area (EEA), reduced by five years and cannot be more than 5 years.⁴⁵ Of course, a SPC can be granted only if there is a patent in force.⁴⁶ This Regulation was repealed by Regulation 469/2009, but there were made no significant changes. A Regulation worth mentioning is 1901/2006 concerning medical products for pediatric use, since it provided with the extension of the SPC for 6 more months.⁴⁷

⁴³ (Χρυσάνθης, 2012), p. 730.

⁴⁴ (Viorel, 2015), p. 18.

⁴⁵ (Grubb, 1999), pp. 148- 150.

⁴⁶ (Portal, 1991), p. 986.

⁴⁷ (Viorel, 2015), p. 19.

The *scope of the SPC* is not to extend the entire pharmaceutical patent, but to preserve the protection given to the product covered by the marketing authorization.⁴⁸ The Regulation tries to put some quality and quantity limits regarding the SPC.⁴⁹ The sales of the product for non-medical use is not an infringement.⁵⁰ The subject – matter of the SPC is the “product”; the “*active ingredient or combination of active ingredients of a medical product*”.⁵¹ Unfortunately, applicants seem to be reluctant as regards SPC, since they are not certain which is the exact “product” that is protected by it; the active ingredient in every possible formulation or in only the specific one for which the authorization was granted? The E.U. Regulation 1768/92 does not seem to give a clear answer to this question. There is no full explanation concerning the identity of the subject – matter of a pharmaceutical patent and that of a SPC.⁵²

However, guidance seems to be given about this issue by Regulation 1610/1996. If the pharmaceutical SPC is interpreted according to the latter Regulation, then whether a granted pharmaceutical patent covers also other forms of the product, the SPC also covers them, even if the marketing authorizations was for only one form.⁵³ This is of great importance, since it clears all the uncertainty that discouraged pharmaceutical companies from applying for an SPC and promotes its existence.

Moreover, a decision made by the European Court of Justice (ECJ) has widened the possibility for obtaining a SPC. According to *Neurim Pharmaceuticals (1991) Ltd v. Comptroller – General of Patents case* (19th of July 2012), the interpretation of articles 3 and 4 of Regulation 469/2009 is the following. In case there was an earlier marketing

⁴⁸ (Portal, 1991), p. 988.

⁴⁹ (Viorel, 2015), p. 21.

⁵⁰ (Grubb, 1999), pp. 222-223.

⁵¹ (Viorel, 2015), p. 21.

⁵² (Viorel, 2015), p. 21.

⁵³ (Grubb, 1999), pp. 222-223.

authorization for the active ingredient for a different use in a different species, then this earlier authorization does not preclude the grant of a SPC for a different application. But even if there was a case where there was an earlier marketing authorization in the same species, the ECJ made it clear that the interpretation of the articles would be the same and that the grant of an SPC would be possible.⁵⁴ This European Court of Justice (ECJ) decision encourages even more pharmaceutical companies to invest in research and innovation.

THE ECONOMICAL AND TECHNOLOGICAL USE OF PHARMACEUTICAL PATENTS

The first modern pharmaceutical industry began to exist during the end of the 19th century, when scientists discovered that some raw materials had antiseptic effects. Enterprises such as Ciba – Geigy, Roche and Sandoz, which have first started as family businesses in Switzerland, moved to the production of pharmaceutical substances and became some of the most powerful pharmaceutical companies. One of the reasons behind the massive evolution of pharmaceutical industry was W.W.II and the urgent need for antibiotics.⁵⁵

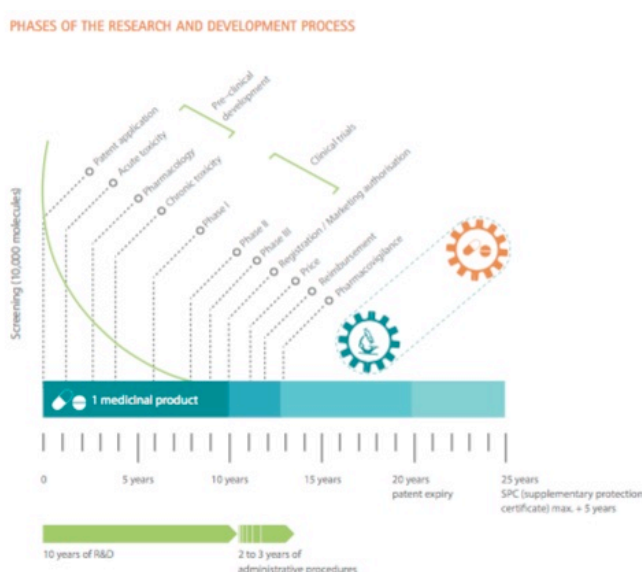


Figure 3: Phases of a medicine's production

Source: The European Federation of Pharmaceutical Industries and Associations (EFPIA), 2016, <http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf>.

As regards the pharmaceutical industry, patents normally equal the product, and pro-

⁵⁴ (Neurim Pharmaceuticals (1991) Ltd v. Comptroller - General of Patents, 2012).

⁵⁵ (Φαρμάκης, 2012), pp. 12-13.

tect the extensive investment in research and clinical testing required before placing it on the market.⁵⁶ It is thought that, for the creation of a new and successful medicine, scientists need to spend approximately 10 to 15 years for studies, research, clinical tests, price fixation etc.⁵⁷ (Figure 3: Phases of a medicine's production). During these years, more than hundreds of people are obliged to work on this project to accomplish it. From every 5,000 to 10,000 pharmaceutical products, that insert research and production, only one of them makes it successfully to the pharmaceutical market and is commercially exploited. The amount of money needed from the beginning of research until the medicine joins the market is considered to be approximately \$800,000,000 to \$1,000,000,000 per medicine. All these huge capitals are mainly private and it is only logical that they head towards investments that can secure pure profit.⁵⁸

Pharmaceutical patents have a *technological reason* behind their existence. According to Patent Law, not only in Greece, but almost in every country around the world, a patent must describe the invention in details and include all these features that make it so unique, innovative and new. It can be published months after the claim of its grant is filed. After the publication, researchers and scientists are allowed to study it. Due to that, technological information is spread to others and so does knowledge and the spirit of innovation and healthy competition between pharmaceutical companies.⁵⁹ Moreover, the fact that patents grant a pharmaceutical company the right to protect its pharmaceutical substances for a period of time, operates as a reward towards their efforts and promotes their motive for further research and innovation.⁶⁰

Patent protection for chemical and pharmaceutical products is especially important,

⁵⁶ (Lehamn, 2003), p.2.

⁵⁷ (Φαρμάκης, 2012), p. 14.

⁵⁸ (Μπάλλας, 2010), p. 3.

⁵⁹ (Μπάλλας, 2010), pp. 3-4.

⁶⁰ (Φαρμάκης, 2012), p. 26.

compared to other industries, because the actual manufacturing process is often easy to replicate and can be copied with a fraction of the investment of that required for the research and clinical testing. A medicine, of course, cannot be protected forever. After the expiry of the patent, the medicine falls into the public domain and everyone is free to make use of it. That seems to be unfair, since a company has spent great amounts of money, as it was mentioned above, to create the medicine.

The imitation and the copy of a successful medicine is not only easy, but also cheap as a process, since the cost of a medicine's production is lower than the investment made for its research in the first place. As a result, the risk that is taken by an investment to be easily imitated later by other companies and lose a lot of money, is a risk that discourages new investors from offering money to innovation and new research in the pharmaceutical industry.⁶¹ That incident can only cause problems to patients - consumers and healthcare, since pharmaceutical companies and scientists are discouraged from trying to find the cure for diseases that make people suffer or help patients be more comfortable thanks to new medicines which are more effective and suitable. The research of new pharmaceutical substances is sure to hide a great risk for pharmaceutical companies and so many European companies tend to transfer to the United States (U.S.), since they provide a friendly environment that welcomes companies and their investments.⁶²

Patents in the pharmaceutical industry are trying to reverse this, since they give the investors the protect they need. The "pharmaceutical patent" gives a company the right to have a monopoly as far as the specific medicine is concerned and thus only this company can make profit from its sale in the pharmaceutical market. After that it becomes clear that *pharmaceutical patents* do also have an *economic use*.

⁶¹ (Μπάλλας, 2010), p. 3.

⁶² (Φαρμάκης, 2012), p. 14.

COMMERCIAL EXPLOITATION OF PHARMACEUTICAL PATENTS

The pharmaceutical market is one of the most powerful markets worldwide and should not be taken light – hearted. According to European Federation of Pharmaceutical Industries and Associations (EFPIA) report, 27 million euros were spent in the E.U. in 2010 in the departments of research and development of the pharmaceutical industry.⁶³ It is essential to mention that no pharmaceutical product is allowed to be circulated in the European pharmaceutical market unless a marketing authorization has been first granted (article 3(1) Regulation 726/2004).⁶⁴

THE PHARMACEUTICAL MARKET

Pharmaceutical market seems to behave differently compared to other markets (Figure 4: The European Pharmaceutical Industry). One of the reasons behind this conclusion is the fact that it is characterized by some special features which are not met in other markets, since it is a subcategory of the healthcare market.⁶⁵ The most important difference that is spotted in the global pharmaceutical market and that distinguishes it from all the other markets is, according to my opin-



INDUSTRY (EFPIA total)	2000	2010	2014	2015
Production	125,316	199,400	221,088	225,000 (€)
Exports (1) (2)	90,935	276,357	324,452	381,500 (€)
Imports	68,841	204,824	251,427	275,000 (€)
Trade balance	22,094	71,533	73,025	86,500 (€)
R&D expenditure	17,849	27,920	30,887	31,500 (€)
Employment (units)	534,882	670,088	723,448	725,000 (€)
R&D employment (units)	88,397	117,035	118,052	118,000 (€)
Total pharmaceutical market value at ex-factory prices	86,446	153,118	183,924	192,000 (€)
Payment for pharmaceuticals by statutory health insurance systems (ambulatory care only)	76,909	129,464	124,273	126,000 (€)

Figure 4: The European Pharmaceutical Industry

Source: The European Federation of Pharmaceutical Industries and Associations (EFPIA), 2016, <http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf>.

⁶³ (Φαρμάκης, 2012), p. 27.

⁶⁴ (Κρεμαλής, 2011), p. 735

⁶⁵ (Καφετζής, 2013), p. 18.

ion, the almost full separation between consumers and purchasers of the product.⁶⁶

PHARMACEUTICAL MARKET'S CHARACTERISTICS

First of all, pharmaceutical market is a part of the healthcare market which is controlled by *"information asymmetry"*. By this term, it is meant that, most of the times, the patient is not capable of understanding the medical condition nor the treatment needed. People who have not gained medical experience by having health studies are unable to control a situation of illness and to decide the necessary treatment. Thus, a knowledge asymmetry can be seen between patients – consumers and medical practitioners – producers. Due to the existence of that asymmetry, patients – consumers are not the ones in charge. On the contrary, the leader seems to be the medical practitioner – producer, who prescribes the appropriate medicine needed for a cure to be achieved (*"consumer sovereignty"*). Because of this gap that exists between patients and medical practitioners, an *"agency relationship"* is built. Patients cannot act by themselves as individuals. They are *"represented"* by their medical practitioners who actually choose the best treatment for them, on behalf of them. Unfortunately, there are no clear choices which are made exclusively by consumers as it happens in the free market.⁶⁷

Secondly, there is also the *"moral hazard"*. The insurance company or organization, according to each country's legislation, is obliged to return to the patient the economic burden caused due to the illness, the value of the medicine. Neither the patient nor the medical practitioner care enough about the costs of a medical treatment, since the burden is to be carried by a third party (*"third party payer"*).

Last but not least, there are also the positive and negative *"externalities"* that concern the costs and profits made by medical practitioners and patients. They move from them to both society and the environment and provoke changes to them. For example,

⁶⁶ (Καφετζής, 2013), p. 18

⁶⁷ (Καφετζής, 2013), pp. 13-14.

vaccination for the prevent of an epidemic is an externality that can protect a person from getting sick or from transmitting a disease to another person.⁶⁸

In my opinion, these characteristics are the main reason behind the failure of healthcare market as it is structured and the reason why the right in health must be treated as a free and public right.

DEMAND AND OFFER IN THE PHARMACEUTICAL MARKET

It is already mentioned that in the pharmaceutical market the patient – consumer is not the one who takes the decision concerning the choice of medicines. Demand in pharmaceutical market is not estimated only by consumers, but by many factors. Medical practitioners, insurance organizations, pharmacists and the patient interact.⁶⁹ As a result, “*imperfections*” are caused in the pharmaceutical market that affect demand and cause perfect competition to become unbalanced.

Demand is split into four dimensions:

- i. To the “*customer*”, who is the medical practitioner,
- ii. To the “*payer*”, who is the insurance company or organization, depending on the country’s legislation,
- iii. To the “*distributor*”, who is the pharmacist and
- iv. To the “*consumer*”, who is the patient.⁷⁰

It is only logical, to me, that demand numbers cannot be granted with stability, since there are many factors that can cause the scale to move towards different directions. Diseases that torture patients are not always the same and can change, depending on the patient’s age and the period (for example seasonal influenza).

⁶⁸ (Καφετζής, 2013), p. 14.

⁶⁹ (Καφετζής, 2013), p. 20.

⁷⁰ (Καφετζής, 2013), p. 21.

This is also boosted by these facts. Consumption, thus demand, in the pharmaceutical market is affected by five factors:

- i. *By the factor that finances the pharmaceutical market*, for example the government, the insurance organization or even the patients themselves, whether they pay for the medication.
- ii. *By demographic factors*, since the rise of life expectancy increases the demand of medicines for elderly people who need them in greater and more specific amounts.
- iii. *By epidemiological factors*, since diseases are the main cause that pushes patients to the pharmaceutical market.
- iv. *By social and economic factors*. Ever since poverty has started to eliminate in many social statuses, people are more capable to afford medication. Moreover, the dissemination of the need of education has played an important role in the change of pharmaceutical's demand. This, on the other hand, was impossible when people were not as educated and as sensitized as today and is still impossible in less developed countries where poverty thrives.
- v. *By healthcare factors*. Nowadays, more and more medical practitioners exist and more medicines, that cure illnesses that used to be fatal, appear. Thus, people tend to care more about their health and their treatment.⁷¹

As far as offer is concerned, there are also some particularities. The main one is the result of monopoly that is granted to pharmaceutical companies by pharmaceutical patents.⁷² It becomes clear, more than once, in my opinion, that pharmaceutical patents do not only grant companies with rights that make them feel secure, they also have an economic use. They built an entire market that is adjusted by this right and could possible fall off like a paper castle once this right is taken away. It is vital that it is well understood that balance in the pharmaceutical market is kept by a very thin rope.

⁷¹ (Καφετζής, 2013), p. 22.

⁷² (Καφετζής, 2013), p. 23.

The main characteristics, that adjust offer in the pharmaceutical market are the ones mentioned below:

- i. The minimize of costs and the maximize of investments to succeed long-term profit.
- ii. Mergers and acquisitions in the global pharmaceutical market and
- iii. The classification of pharmaceutical companies into three categories. First, the big multinational pharmaceutical companies, which, of course, are the most powerful ones. Second, the pharmaceutical companies that are capable of the produce of prototypes, but focus only in the produce of generics. Third, the pharmaceutical companies that operate in a more “family business” manner and are not as powerful as the previous ones.⁷³

To sum up, *according to the WHO*, the *adjustment of the pharmaceutical market* is characterized by three facts. First, by the “*product regulation*”, where medicines are checked and evaluated before and after they enter the market. Second, by the “*adjustment of the manufacture, import and distribution*” of the medicines in the market. Third, by the “*adjustment of commercial promotion of medicines*”.⁷⁴

THE PHARMACEUTICAL INDUSTRY IN GREECE

In Greece, in 2013, 56 multinational and 50 national pharmaceutical companies, 120 medicine warehouses, 27 medicine partnerships and 11,000 pharmacies existed, so it can be concluded that pharmaceutical industry is vital for Greece’s economic development.⁷⁵ According to facts given by the Panhellenic Union of Pharmaceutical Indus-

⁷³ (Καφετζής, 2013), pp. 25-26.

⁷⁴ (Καφετζής, 2013), pp. 26-27.

⁷⁵ (Healthmag.gr, 2016).

try (PEF), some examples of Greek pharmaceutical companies are Adelco, Demo, Elpen, UNI – PHARMA, VIANEX.⁷⁶

THE GREEK PHARMACEUTICAL MARKET

The Greek pharmaceutical industry, even though Greece is in economic depression, is not limited. Greek companies produce various generic medicines that are exported to countries not only in Europe, but in four continents.⁷⁷ However, Greek pharmaceutical companies do not only produce generics. They also create new medicines. (Figure 5: Example of Greek Pharmaceutical Patent Certificate). For example, the Greek pharmaceutical company Elpen has a very strong intellectual property portfolio. “*Elpenhaler*”, an inhaler device, has been granted more than 90 patents in many countries both European and non-European.⁷⁸

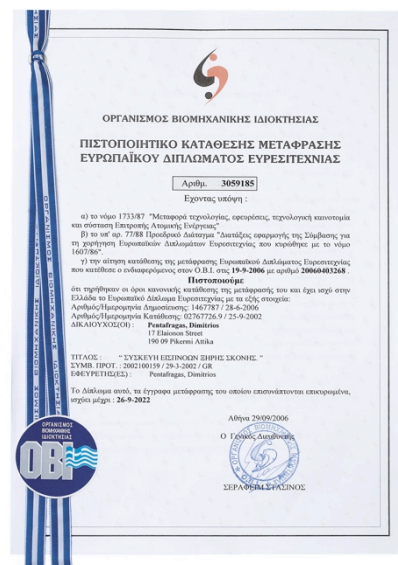


Figure 5: Example of Greek Pharmaceutical Patent Certificate

Source: Elpen Pharmaceutical (2016), <http://www.elpen.gr>.

“*SALOSPIR*”, a well-known medicine, was created by the Greek company UNI – PHARMA. The decision made by the Greek Court concerning a dispute between BAYER AG. and UNI – PHARMA S.A. cannot be forgotten, since it is positive towards the Greek pharmaceutical company and analyzes in depth and in a correct manner the difficult issues that concern medicines, their packages, how consumers interact with the view of the medicine’s package and how all these can affect pharmaceutical competition. The main conclusion made by this judgement is that pharmaceutical products’ reputa-

⁷⁶ (Πανελλήνια Ένωση Φαρμακοβιομηχανίας, n.d.).

⁷⁷ (Elpen, n.d.).

⁷⁸ (Elpen, n.d.).

tion is built by their name and not by their packaging colors, as BAYER tried to state.⁷⁹ This judgment can and will have a major effect on pharmaceutical competition law not only in Greece, but also in E.U. In my opinion, it is a huge win for a Greek pharmaceutical company against a colossus German one in today's Greece, despite the economic depression that limits, in most cases, its pharmaceutical industry's capability. Thus, Greek pharmaceutical market is an active one that also contributes in the global pharmaceutical industry.

THE "GENERIC PARADOX"

Many Greek pharmaceutical companies focus on the production of generics. Generics can provide high profit due to their lower price and cost of manufacture.⁸⁰ Generic medicines enhance competition, since they are cheaper than the prototypes but have the same effects as them. As a result a lot of people prefer to purchase them instead of the more expensive archetype medicine. The E.U. also tries to promote generics over prototypes in a way to decrease the member – States costs in social insurance and to use these capitals in order to enhance innovation and as a result competition.⁸¹ Unfortunately, there is the "*generic paradox*". According to this phenomenon, even if there is a huge insertion of generics in the pharmaceutical market, that could not effect so massively competition and as a result the prices of the prototypes. It could only just slow down the rhythm of the increase of prices. The reason behind this paradox is that even though generics exist in huge numbers in the market, their purchase is effected by the medical practitioners' prescriptions and not by consumers, as it has already been mentioned. It is prescription the factor that gives form to demand.⁸²

⁷⁹ (Η Καθημερινή, 2015).

⁸⁰ (Φαρμάκης, 2012), p. 51.

⁸¹ (Φαρμάκης, 2012), p. 53.

⁸² (Φαρμάκης, 2012), p. 55.

PHARMACEUTICAL PATENTS AND COMPETITION LAW

Even though China and India have tried to progress during the last years, the biggest part of the global pharmaceutical market is in Europe and the U.S. (Figure 6: The World Pharmaceutical Industry (2010)). The U.S. controls the 38,1% of the global pharmaceutical market, Europe the 36,1%, while Japan and other countries only the 7,7% and 18,1%. Though it seems like the U.S. pharmaceutical market has flourished during the last two decades (Figure 7: Sales in the Pharmaceutical Market (2015)), since many

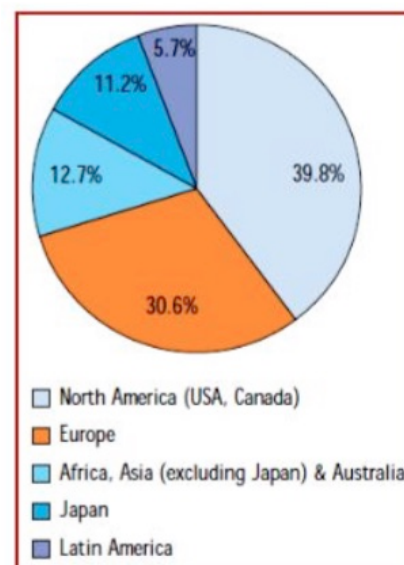


Figure 6: The World Pharmaceutical Industry (2010)

Source: Φαρμάκης Κωνσταντίνος,

<http://nemertes.lis.upatras.gr/jspui/bitstream/10889/5280/1/Farmakis%20Constantinos.pdf>, p. 17.

companies were transferred there, on the contrary, the European pharmaceutical market's production has in-

creased compared to the investments made and it could even be stronger than the U.S. market.⁸³

One of competition goals is to make sure that pharmaceutical companies can enter a market which is large enough not only to bear the costs of developing new medicines, but also to make enough profit, so that more research and development is inspired. The definition of healthy, fair and workable competition does not exist in the Treaty of Functioning of the European Union (TFEU), but can be concluded by the case law of the ECJ. For a competition to be effective it is essential that the market is structured in a competitive manner. A workable competition must be in position to accomplish three main results:

- i. *"Allocate efficiency"* (price fixation),
- ii. *"Productive efficiency"* (lower prices that are closer to factory prices) and

⁸³ (Φαρμάκης, 2012), p. 17.

iii. “Innovative efficiency” (more research).⁸⁴

The EU is trying to accomplish this by many means. *The first*, and the most important one, in my opinion, is the harmonization of legislation, concerning pharmaceutical patents and competition law, throughout the E.U. member – States. *The second*, which has already been analyzed in the previous chapter, is that the E.U. pharmaceutical industry recognizes a special privilege for pharmaceutical patents, the SPC. *The third* is that E.U. competition law strives to promote single market integration, so that pharmaceutical market will not be divided in national level.⁸⁵ Of course, the existence of harmonized legislation concerning patent law and especially pharmaceutical law is also the key behind the success of the above. The link between patents and competition is, nevertheless, more obvious than ever. Provided there is effective pharmaceutical patent protection in E.U., would pharmaceutical market be productive and profitable for all interested in it. Maire Geoghegan – Quinn, E.U. Commissioner for Research has claimed that “innovation is vital for a successful modern economy, it is as important as water for life...”⁸⁶

On the contrary, there is an opinion which argues with the above. There are critics who



Figure 7: Sales in the Pharmaceutical Market (2015)

Source: The European Federation of Pharmaceutical Industries and Associations (EFPIA), 2016,
<http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf>.

⁸⁴ (Σταματούδη, 2006), p. 39.

⁸⁵ (Hancher, 1992), p. 387.

⁸⁶ (Φαρμάκης, 2012), p. 24.

question the link between patents, innovation and healthy competition in the field of pharmaceutical market. They claim that there is no proof of a link between them and that pharmaceutical companies do not focus on innovation and the development of the most urgent and lifesaving medicines, but on the development of the most profitable ones. It is true that in the U.S. pharmaceutical market the profit made of the blockbuster medicines is immense.⁸⁷ Professor Sager has pointed out that since patents are extended and general, pharmaceutical companies are used to operate like monopolies.⁸⁸

An issue that enhances this belief is that of “*Daraprim*” medicine (U.S.). Daraprim is used by people that are infected by IHV, produced by the Turing Pharmaceutical. This medicine is 62 years old and is used against toxoplasmosis. Unfortunately, the pharmaceutical company has decided to increase its cost from 13,50\$ to 750\$, because the previous price could not make enough profit for the company. Thus, in India a pill could cost around \$0.05, in U.K. around \$0.66, while on the other hand in the U.S. \$750! Even though this medicine is not protected by patent law, the pharmaceutical company has indeed a great monopoly over it, since other pharmaceutical companies need to file an “*abbreviated new drug application*” (ANDA) that could allow to their generics to register in the U.S. pharmaceutical market. Unfortunately, no company is interested in that, because of the small market share that this medicine represents and of the risk that Turing Pharmaceutical could possibly lower the price again for profit.⁸⁹

In my opinion, the reason behind the existence of pharmaceutical patents is indeed the promotion of innovation and fair and healthy competition. Even though numbers seem to show that pharmaceutical companies earn great amount of money due to patents and the monopoly that they create, it is not to be forgotten that they also spent enormous amounts in research and innovation. Only if there is the feeling of security,

⁸⁷ (The Wall Street Journal, 2012).

⁸⁸ (Boldrin and Levine, 2005), p. 11.

⁸⁹ (Gottwalt, 2015).

will pharmaceutical companies be able to invest into research and medicines. Otherwise, high risk investments will discourage the fund owner's. Balance between research and innovation in medicines and fair competition will be destroyed with fatal results for healthcare. It is imperative that balance is the beginning and the end of every new measure taken to manage the pharmaceutical market and its areas and not to wrong neither patients – consumers' nor pharmaceutical companies' interests and prerogatives.

PHARMACEUTICAL PATENTS AND PARALLEL IMPORT

Another important key that plays a crucial role in the European pharmaceutical market is medicines' prices. This issue has indeed created a division through the E.U. market that has been expressed through *parallel import* (Figure 8: Parallel Import in the E.U. Pharmaceutical Industry).

There are two types of pharmaceutical parallel import:

- i. The first type concerns *the phenomenon of parallel imports*. According to it, a medicine is produced in two or more different countries and is then sold in different "ex-factory prices".

Sometimes these factories are owned by the same pharmaceutical company that also owns the pharmaceutical pa-

tent. The medicine is purchased by a supplier in a country with the lower ex-factory price and is exported towards the country with the higher ex-factory price.

SHARE OF PARALLEL IMPORTS IN PHARMACY MARKET SALES (%) – 2014

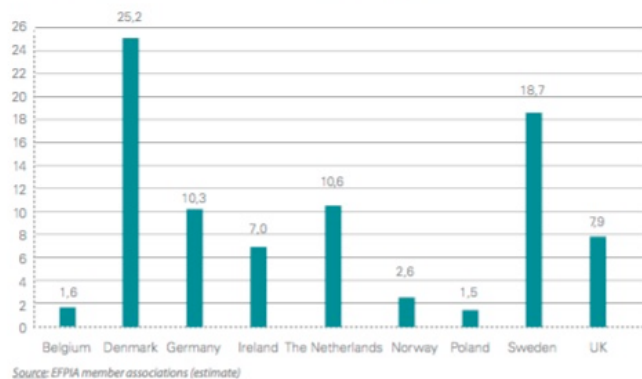


Figure 8: Parallel Import in the E.U. Pharmaceutical Industry

Source: The European Federation of Pharmaceutical Industries and Associations (EFPIA), 2016,

<http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf>.

- ii. The second type concerns *the phenomenon of parallel re-imports*. According to it, the same pharmaceutical company exports a medicine in a lower price than the price that it is sold inside the country. The price is adjusted to the lower price that exists in the import – country. It is also possible that the pharmaceutical merchants of the import – country do intend to re-export the medicine in order to gain more profit.⁹⁰

Unfortunately, these kinds of movements have many side-effects. Shortages in medicines can be detected in the re-export – countries and identical medicines are re-imported from low cost countries to higher cost ones in order to make more profit by the lower price. The expiration of a series of patents does not help with this problem. Generic competition and the positive position of the E.U. and ECJ towards them also point to a more fair and healthy pharmaceutical market.⁹¹ A market that seems, as years are passing by, that is healthier, united and not the privilege of a few strong companies, and that cares more deeply for the better good of people. After all, pharmaceutical industry's goal should be the ensuring of people's health and the fight of illnesses, since the most important good in a person's life is health and well-being. The E.U. is taking into consideration both consumers' and the companies' rights.

According to the *E.U. law*, there are two sets of rules relevant to patents: the *competition rules* and the *rules on the free movement of goods*. The EU Competition Law tries to protect competition in E.U. market and to promote the efficient use and dissemination of goods and services throughout the E.U. It cannot be omitted that one of the fundamental objectives of the E.U. Treaty was the creation of a Common Market, where goods will be circulated freely, with only a few exceptions.⁹² One of these exceptions is that E.U. law seems to recognize the existence of patents given by member – States with some limitation. There are some concepts that Courts should take into

⁹⁰ (Γκόλνα, Κοντιάδης and Σουλιώτης, 2005), p. 29.

⁹¹ (Hancher, 1992), pp. 389-390.

⁹² (Travers, 1998), p. 47.

consideration when deciding about such conflicts:

- i. The “*dichotomy*” between the *existence* and the *exercise* of patents,
- ii. The specific “*subject – matter*” of the patent and
- iii. The *exhaustion of patent rights*.⁹³

An important case concerning the issue of parallel import is the *Centrafarm BV and Adriaan da Peijper v. Sterling Drug INC case*. The Sterling Drug company was granted patents for both the U.K. and Netherlands regarding a medicine against urinary tract infection (UTI). The same medicine was sold in the U.K. for half price compared to Netherlands, since the U.K. had strict legislation concerning pharmaceuticals’ price fixing. Centrafarm company was specializing in pharmaceuticals’ parallel import and imported a great amount of this medicine in Netherlands with the intension of selling it. Sterling Drug tried to block this by using its Netherlandish patent. According to the ECJ, the scope of patent is the reward of the inventor for the creation. The pharmaceutical patent’s owner has the exclusive right to circulate the medicine in the E.E.A.. In this case, Sterling Drug was rewarded for the creation of the medicine by putting it in the U.K.’s market and making profit out of it, so its right was exhausted. The ECJ could not allow Sterling Drug to block the import of the medicine from the U.K. to Netherlands. If it did so, it would cross the lines of free movement of goods inside the E.E.A..⁹⁴ As it can be concluded, the main criterion of whether parallel import is legal or illicit is whether the exhaustion of the patent right has occurred in the E.E.A..⁹⁵

Although to some it may seem that there is a clash between competition and patents, the truth is that patents, and generally intellectual property rights, promote healthy competition and consumer’s welfare. Pharmaceutical patents are imperative, since they encourage research, innovation and investments. They also allow consumers –

⁹³ (Jones and Sufrin, 2014), pp. 853-854.

⁹⁴ (Σταματούδη, 2006), pp. 64-65.

⁹⁵ (Χρυσάνθης, 2012), p. 2.

patients to obtain information about the medicines and choose between them, of course on the quota that they are free to choose. To create a strong single and united European market, balance is needed among the different competing interests.⁹⁶

THE ASTRAZENECA CASE

One probably of the most important competition law pharmaceutical cases of the last decade is *case C-457/10 P, AstraZeneca A and AstraZeneca plc v. European Commission (2012)*. The AstraZeneca case is a positive one regarding generics. A lot of articles and books were written for this case, which seems to affect the way European pharmaceutical industry works.

*According to the ECJ, AstraZeneca has committed two abuses of dominance (Article 102 TFEU) of the patent system. It has made “misleading representations” of certain dates to national patent offices to extent the protection granted to one of its blockbuster gastrointestinal treatments (“Losec”) by SPC.⁹⁷ Moreover, by selective deregistration of its medicine’s older form, it has not allowed pharmaceutical companies to obtain marketing authorization for their generics (Article 4(3)(8)(a)(iii) Directive 65/65).⁹⁸ AstraZeneca demanded the withdrawal of the marketing authorizations in Denmark, Norway and Sweden. However, this action could result the restriction of parallel import of the products to these countries.⁹⁹ As the ECJ stated, *a dominant undertaking “has a special responsibility [...] it cannot therefore use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relating to the defense of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective**

⁹⁶ (Goldberg and Lonbay, 2000), p. xiii.

⁹⁷ (Jones and Sufrin, 2014), p. 558.

⁹⁸ (Mehta, 2012), p. 1.

⁹⁹ (Γρηγοριάδης, 2013), p. 4.

justification". Unfortunately, this approach was a bit narrow, since there was no consideration regarding the case where equally efficient competitors were excluded.¹⁰⁰

AstraZeneca case has many *consequences*. *First*, there is a lowering of the grounds for the existence of an abuse of dominance, since the key behind it the *intention of a dominant* to preclude generics from entering the market.¹⁰¹ The AstraZeneca case has affected the application of article 102 TFEU.¹⁰² *Second*, this case showed the need to analyze the pharmaceutical market and its complex structure. Last but not least, the competent authorities are now triggered to further question patent procedures.¹⁰³

All these consequences are of equal importance, but the most important one, in my opinion, is the first one. A new standard was created as regards abuse of dominance, a standard that is about to change the way pharmaceutical market works. It is vital that since the grounds for accusing a company for an abuse are lowered, balance is preserved. This must not be used thoughtlessly by companies that wish to promote their rights. The main positive idea that should be concluded by this case is that generics will no longer be excluded from the pharmaceutical market by any abuse of the dominant companies.

¹⁰⁰ (Mehta, 2012), p. 1.

¹⁰¹ (Mehta, 2012), pp. 2-3.

¹⁰² (Γρηγοριάδης, 2013), pp. 4-7.

¹⁰³ (Mehta, 2012), pp. 2-3.

THE ISSUE OF “ACCESS TO MEDICINES”

Two main issues were discussed regarding science, legislation and case law of pharmaceutical patents. The first one concerns the legality of their existence and the second one the consequences of TRIPS Agreement. TRIPS

Agreement clearly seems to recognize the grant of

pharmaceutical patents.¹⁰⁴ However, the mere existence of pharmaceutical patents seems to create problems regarding access to medicines.

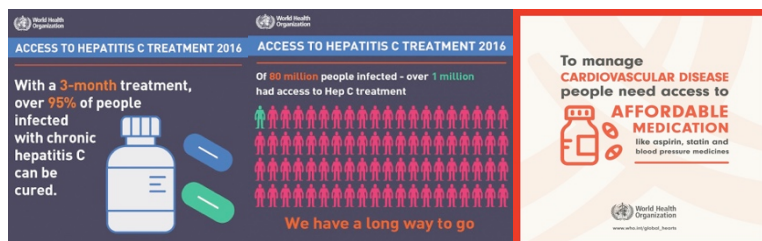


Figure 9: Pictures used by WHO for access to medicines.

Source: (The World Health Organization (WHO), 2016)

THE PROBLEM

The issue of “access to medicines” is a complicated one. It concerns the global political economy and involves many political, social, economical, medical and moral dimensions (Figure 9: Pictures used by WHO for access to medicines.). Nowadays, access to medicines is becoming a priority concern both for developing and developed countries. The high prices of medicines and the exacerbation of diseases, especially in developing countries, make it impossible for some patients to have access to them. Public interests are crucial to be protected.¹⁰⁵ Moreover, TRIPS Agreement seems to help the rise of prices for patented medicines and to make access to medicines more difficult.¹⁰⁶

The response to these fears was the adaptation of the *Doha Declaration in 2001*. According to the Doha Declaration, public health was in priority position compared to

¹⁰⁴ (Χρυσάνθης, 2012), p. 699.

¹⁰⁵ (Gurgula, 2017), p. 1.

¹⁰⁶ (Naik, 2006), p. 48.

pharmaceutical patents and some health safeguards were put. *First*, it was emphasized that TRIPS Agreement should not prevent World Trade Organization (WTO) member – States from protecting healthcare rights. *Second*, it was stated that TRIPS Agreement should be interpreted as an agreement that promotes access to medicines. *Third*, there is the provision of compulsory licensing in pharmaceuticals, which can be determined in details by each member – State. The same applies also for parallel import.¹⁰⁷

In 2008, the E.U. Commission began an investigation regarding the E.U. pharmaceutical industry. Unfortunately, the result was not good enough, since most pharmaceutical companies have found ways to extend the commercial life of medicines and to delay the production of generics.¹⁰⁸ According to the WHO, fair access to safe and affordable medicines is crucial for a high-level healthcare. To enhance this, WHO member – States adopted, in 2008, a resolution on *“Global strategy and plan of action on public health, innovation and intellectual property”*.¹⁰⁹ A new international treaty named Anti-Counterfeiting Trade Agreement (ACTA) is being discussed and negotiating between developed countries to help in a vital manner the issue of access to medicines.¹¹⁰

PHARMACEUTICAL PATENTS LICENSES

Pharmaceutical patent licenses enhance not only access to medicines but also the further development of the pharmaceutical market. It is considered that patent acquisitions and their transfer is promoting competition.¹¹¹ They enhance the dissemination of technology and innovation.¹¹² Whether a pharmaceutical company is an ethical one,

¹⁰⁷ (Naik, 2006), pp. 48-52.

¹⁰⁸ (Gurgula, 2017), p. 1.

¹⁰⁹ (World Health Organization (WHO), 2009).

¹¹⁰ (Lee, 2010), p. 42.

¹¹¹ (Gurgula, 2017), p. 1.

¹¹² (Jones and Sufrin, 2014), p. 858.

it will respect the pharmaceutical patent of another and would seek for the grant of a license.¹¹³

Pharmaceutical patent licenses are the solution given to a manufacturer, when the pharmaceutical product that he/she wishes to sell is protected by another's patent. They involve the grant by the patent owner of a license to the licensee that authorizes the licensee to exploit this patent, usually in return for the payment of royalties.¹¹⁴

According to article 102 TFEU, neither dominance nor its creation and preservation is prohibited.¹¹⁵ It only prohibits its abusive use.¹¹⁶ There are cases where pharmaceutical patent owners refused to license third parties and to give them the right to exploit these rights. This refusal is abusive, when more dominant companies seem to take advantage of their position against the less dominant ones. However, for this provision to be used, someone must first prove that the pharmaceutical company that refused to grant the license is a dominant one in the relevant product and geographic pharmaceutical market.

It appears to exist some tension between patents and competition law, since the first grants exclusivity, while the second is in favor of free competition. As the *article 345 TFEU* states, «*the Treaties shall in no way prejudice the rules in Member – States governing the system of property ownership*».¹¹⁷ Thus, the EU legislation and article 102 TFEU are not able to annul patents. To solve this problem, the EU case law developed the *doctrine of «dichotomy»* of the existence and exercise of intellectual property rights. This doctrine states that article 102 TFEU is not allowed to affect the existence of pharmaceutical patents. Only their exercise can be reviewed by the E.U. Law. The

¹¹³ (Grubb, 1999), p. 396.

¹¹⁴ (Grubb, 1999), pp. 395-396.

¹¹⁵ (Official Journal of the European Union, 2012), article 102 TFEU.

¹¹⁶ (Lamping, 2015), p.6.

¹¹⁷ (Official Journal of the European Union, 2014), article 345.

list in article 102 TFEU is a non-exhaustive one. «Abuse» is a legal term that needs further interpretation.¹¹⁸ Article 102 TFEU considers that an abusive refusal to license can take several forms, depending on the circumstances of the case.¹¹⁹ However, a refusal to license must be taken in consideration when the medicine is objectively necessary and when the refusal could harm fair competition in the downstream market and the patients – consumers.¹²⁰

However, pharmaceutical companies seem to find several ways, sometimes even a combination of them, to protect their medicines against generics. A typical example is the *Perindopril case (2014)*. According to the Commission, *Les Laboratoires Servier*, a French pharmaceutical company, has started an anti-generics strategy from 1990s. It protected its most popular medicine, “*Perindopril*”, by patents and reverse payment settlements. Servier’s patent practice was complicated and was consisted by many smaller key patents that covered the basic one. It also developed a filing for blocking patents strategy. The Commission found that these acts were violating E.U. Competition Law and especially article 101 TFEU and article 102 TFEU as an abuse of dominant position.¹²¹ Of course, it is essential that competition authorities first take into consideration whether the pharmaceutical company possesses substantial market power in the pharmaceutical market and whether these acts enhance its monopoly, in order to claim that there is indeed a case of abuse of dominant position.¹²²

Another case concerning licenses is the *Genentech Inc. v. Hoechst GmbH case*. *Genentech*, a U.S. pharmaceutical company, could use the “*HCMV enhancer*” to produce proteins for research purposes and for new products that would be sold in return for

¹¹⁸ (Lamping, 2015), p.7.

¹¹⁹ (Lamping, 2015), p.8.

¹²⁰ (Ezrachi, 2011), p. 103.

¹²¹ (Gurgula, 2017), pp. 2-3.

¹²² (Gurgula, 2017), p. 4.

agreed royalties, according to the license agreement that it has signed with Hoechst, a German biotechnology company. The license provided by the agreement was a non-exclusive one. Unfortunately, Genentech failed to pay any royalties and then informed *Sanofi – Aventis* (Hoechst's subsidiary company) its wish to terminate their agreement. Hoechst filed for the settlement of dispute via arbitration in the International Court of Arbitration (ICC). According to the award, Genentech was found wrong and obligated to pay any royalties owed. On the other hand, Genentech's opinion was that this award was a violation of Article 101 TFEU. The ECJ stated that Article 101 TFEU should not be interpreted in way that it precludes the payment of royalties provided by a license agreement, even if the same agreement provides the right to terminate the license by a reasonable notice.¹²³

COMPULSORY LISENCING

The definition provided by the WTO states that *compulsory licensing* is when a State “...allows someone else to produce the patented product or process without the consent of the patent owner”. The main difference that occurred after Doha Declaration was that there was also a provision for least – developed countries and countries that did not have production capacity.¹²⁴

Compulsory licensing in pharmaceutical does not annul the existence of a pharmaceutical patent. The patent owner has all the rights that exist in a patent and also the right to royalties regarding the authorized copies of the pharmaceutical products. Generics that are produced under compulsory licensing are mainly for the domestic market and are not exported to other countries,¹²⁵ thus neither profit nor competition for pharmaceutical companies is harmed. TRIPS Agreement does not enlist specific reasons that justify compulsory licensing, but Doha Declaration allows member – States to decide

¹²³ (Blanke, 2016), p. 1.

¹²⁴ (WTO, 2006).

¹²⁵ (WTO, 2006).

freely about them.¹²⁶ In E.U. compulsory licensing is still *unstable*. Even though it is generally agreed that compulsory licensing in pharmaceuticals should exist in “*exceptional circumstances*”, these circumstances are not precisely defined, causing trouble in the interpretation of this term.¹²⁷

However, TRIPS Agreement (article 31) enlists conditions that define compulsory licensing. *First*, that the one interested in applying for compulsory license should have already tried to negotiate a voluntary license, but in vain. Although, if there is a national emergency or an extreme urgency, the scale of the voluntary license can be skipped. *Second*, a compulsory license does not eliminate the need of payment of royalties to the patent owner. Of course, compulsory license is a non-exclusive one, since the patent owner can continue the production of the medicine.¹²⁸ In my opinion, compulsory licensing is a crucial step taken towards the elimination of the problem of access to medicines that can be caused due to pharmaceutical patents.

¹²⁶ (WTO, 2006).

¹²⁷ (Priddis and Constantine, 2011), p. 270.

¹²⁸ (WTO, 2006).

Conclusions

It is concluded by the definitions given that medicine is not a simple term. It is only logical that the industry that deals with medicines is also a complicated one. Pharmaceutical industry's structure is multidimensional and hides many conflicting rights. To balance the situation, the existence of pharmaceutical patents is crucial. However, they must not be used thoughtlessly.

Between the different types of medicines, the one that causes the more disputes in the pharmaceutical industry is the generic one. Generics enhance competition and are the solution to the problem of access to medicines, however the one-sided promotion of them will destroy the whole pharmaceutical market. Investors will no longer give funds to innovative research and archetype companies will be financially destroyed. Pharmaceutical patents are imperative in this industry to protect the prototypes' rights. There is an obvious interaction between pharmaceutical patents and generics. The end of a patent is to be considered the beginning of a generic. If patents did not exist, generics would not exist either. The lack of patent protection would cause a chaotic situation, since there would be no distinction between an archetype medicine and a generic one.

On the one hand, pharmaceutical patents ensure a legal monopoly in the market, as regards the prototypes pharmaceutical companies, as a form of reward for their innovation and as motivation for further and unstoppable high (in quality and quantity) investment in the pharmaceutical market and technology. The costs of the production of new medicines are sky-high and companies need to make profit to continue their good work. As it is used in every market, in the pharmaceutical industry profit plays a crucial role for funds to be released on research of new medicines. However, in pharmaceutical industry, the common feeling of health and human life enhances more the innovation in research.

On the other hand, healthy competition must not be forgotten in the pharmaceutical market and can be succeeded by the promotion of generics. Pharmaceutical market is a complicated market and it is imperative that its structure is further analyzed my leg-

islaters to create new and more efficient legislation that can both control pharmaceutical patents, without depriving pharmaceutical companies' rights, and promote a healthy competition and thus satisfied patient – consumers. Pharmaceutical market's share is really huge to be divided only by few companies. It could be divided by more companies that can equally offer to healthcare and promote humanity's quality life.

It seems, however, that the whole basis of pharmaceutical market should change. In the pharmaceutical market the patient – consumer is not the one who takes the decision concerning the medicines and demand is estimated by other factors. In my opinion, this is the reason why healthcare deals with so many problems and why pharmaceutical industry's structure should be first mapped and then improved.

The AstraZeneca decision has created a new standard as regards abuse of dominance, a standard that could change the way pharmaceutical market works. But even if the grounds of accusing a company for an abuse are lowered by this ECJ decision, balance should be preserved. This decision must not be used thoughtlessly by generics companies that wish to promote their rights. The main positive conclusion that should be kept is that generics will no longer be excluded from the pharmaceutical market by any abuse of the dominant companies regarding pharmaceutical patents. It seems like the limit needed to safeguard both sides was finally given by the ECJ.

These facts are really important and so every state needs to follow a well-balanced strategy that can promote them. If balance is not kept, healthcare will be hugely hurt and disease and even death rates may rise, especially in developing countries where access to medicines is still under construction. Health is the most important gift given to a person and should be well preserved. Thus, medicines, which actually exist to cure people, should not be unreachable for them. However, since their manufacture requires immense amount of both money and time, pharmaceutical companies should be encouraged to continue research by the safeguard of patent law.

In my opinion, the reason behind the existence of pharmaceutical patents is indeed the promotion of innovation and fair and healthy competition. Even though numbers seem to show that pharmaceutical companies earn great amount of money due to patents and the monopoly that they create, it is not to be forgotten that they also spent

enormous amounts in research and innovation. Pharmaceutical patents interact with the pharmaceutical industry. The extinction of the one would cause the extinction of the other with the form that is known.

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Επιμέλεια από Τμήμα Νομικής, Ερευνητικό Ινστιτούτο Δικονομικών Μελετών,
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